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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/751,493 | 12/28/2000 | Mark A. Burns | UM-04985 | 3280 |

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EXAMINER

SISSON, BRADLEY L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1634 | |

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

918.

Office Action Summary

Application No.

09/751,493

Applicant(s)

BURNS ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The finality of the prior Office action is hereby withdrawn. Prosecution on the merits is reopened.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).
4. Claims 1, 3-13, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,922,591 (Anderson et al.).
5. For convenience, claims 1, 8 and 13, the only independent claims, are reproduced below.

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1. (Three Times Amended) A device comprising:
 - i) a microdroplet transport channel in a silicon substrate, said channel having a depth between 0.35 and 50 μ m, having a width between 50 and 1000 μ m, and connecting to a reaction region; and
 - ii) a series of heating elements arrayed along said microdroplet transport channel, wherein said series of heating elements are configured so as to provide differential heating.

8. (Three Times Amended) A system comprising:
 - i) a microdroplet;
 - ii) first and second microdroplet transport channels in a silicon substrate, said channels having a depth between 0.35 and 50 μ m, having a width between 50 and 1000 μ m, and connecting to a reaction region; and
 - iii) a series of heating elements arrayed along said first and second transport channels, wherein said series of heating elements are configured so as to provide differential heating of said microdroplet by said heating elements.

13. (Twice Amended) A device comprising:
 - i) a first housing portion comprising silicon;
 - ii) a microdroplet transport channel in said first housing portion, said transport channel having a depth between 0.35 and 50 μ m, having a width between 50 and 1000 μ m, and connecting to a reaction region;
 - iii) a second housing portion bonded to and aligned with said first housing portion thus creating an assembled housing, wherein said second housing portion is selected from the group consisting of silicon, quartz or glass; and
 - iv) a series of heating elements in said assembled housing arrayed along said fluid transport channel, wherein said series of heating elements are configured so as to provide differential heating.

6. Anderson et al., teaches at length of devices (applicant's system and device) that are used in the transport and manipulation of biological samples (applicant's "organic material"), including samples that comprise nucleic acids.

7. Anderson et al., column 18, teach that "[f]luid channels. . . will typically range from about 10 to about 1000 μ m wide...and about 1 to 500 μ m deep." This meets a limitation of

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claims 1, 3-13, and 15-17 where the channels are to have a width of from 0.35 and 50 μm and a width of between 50 and 1000 μm .

8. Figures 3, 5A, 5B, 6A, and 6B all depict devices/systems that comprise two or more channels. . Figure 15A clearly depicts a device that comprises a first and second housing and multiple microdroplet transport channels. Such a showing meets the limitation of a “second microdroplet transport channel” of claims 6-20.

9. Column 18 teaches that the device may comprise one or more bodies that are later assembled or mated wherein the bodies comprise optionally comprise fluid channels and reaction chambers. Such “bodies” meet the limitation of applicant’s “first housing portion” and “second housing portion” (claim 13).

10. Column 18, last paragraph, and column 19, last paragraph, bridging to column 20, teach explicitly that the device may be made from silicon or glass, and that in such case, the channels may be manufactured by etching. Such a teaching meets a limitation of claims 4, 7, 11, and 12.

11. Column 20, third paragraph, teaches coating the surface of the device with materials such as silicon oxide and Teflon, and that this can be done in conjunction with the analysis of nucleic acids. This teaching meets a limitation of claims 3, 5, 9, 10, 15 and 17.

12. Column 31, bridging to column 32, teaches fabricating the device so that it comprises “thin film resistive heaters” that are fashioned by sputtering or controlled vapor deposition of a metal onto the surface of the channel. Column 32, first paragraph, and column 35, first paragraph, teach explicitly of providing sufficient number of such heaters in the fluid channel so as to provide for “sample transport.” Said “sample transport” speaks directly to the heaters being in an array and create “differential heating” (claims 1, 8, and 13) of the sample.

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13. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 3-13, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,922,591 (Anderson et al.).

Claim Rejections - 35 USC § 102

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. Claims 1-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5,922,591 (Anderson et al.).

18. See above for the basis of the rejection as it pertains to claims 1, 3-13, and 15-17.

19. Anderson et al., does not teach using heaters made of aluminum (claims 2 and 14), but does teach using metals film generally, however, Anderson et al., column 36, does teach using thermopneumatic valves that comprise aluminum. In view of the "valve" operating by reason of it heating the fluid so to create a bubble that otherwise generates pressure in a line that could block or cause a fluid to flow, one of ordinary skill in the art would have been motivated to have used aluminum heaters in the device.

20. Anderson, column 17, last paragraph, bridging to column 18, teaches fashioning the device from one or more parts, which when brought together, comprises a plurality of fluid transport channels and chambers. Figures 3, 5A, 5B, 6A, and 6B all depict devices/systems that comprise two or more channels. Figure 15A clearly depicts a device that comprises a first and second housing and multiple microdroplet transport channels. Such a showing is considered to meet the limitation of claims 18-20.

21. In the event that Anderson et al., does not anticipate the invention of said claims 18-20, it would have been obvious to one of ordinary skill in the art to have included an array of heating elements in the channels of said device as such would have provided for sample transport.

22. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5,922,591 (Anderson et al.).

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Conclusion


23. Rejections that appeared in the prior Office action and not repeated hereinabove have been withdrawn.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
23 July 2004